

**U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE**

AUDIT REPORT

OF

U.S. GEOLOGICAL SURVEY

AT

DENVER, COLORADO

AUDIT NUMBER USGS-ARC-98-10

APRIL 6 THROUGH 10, 1998

Prepared by: _____ **Date:** _____

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Approved by: _____ **Date:** _____

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1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Audit USGS-ARC-98-10, the audit team determined that the U.S. Geological Survey (USGS) is satisfactorily implementing the Office of Civilian Radioactive Waste Management (OCRWM) QA Program in accordance with the U.S. Department of Energy (DOE) OCRWM Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 7 and USGS implementing procedures for QA Program Elements 1.0, 2.0, 4.0, 5.0, 6.0, 7.0, 12.0, 15.0, 16.0, 17.0, Supplements I, II, and III, and Appendix C.

Although the initial scope of the audit did not identify Supplement V, "Control of the Electronic Management of Data," as applicable to USGS, the audit team assessed potential Supplement V activities both at the Nevada Test Site and in Denver. Based on the USGS activities and methods of verification of information sampled, the audit team determined that this supplement did not apply because electronic data was not used as the controlled source of information. Supplement V may apply to other data management activities at USGS, not within the scope of this audit.

Additionally, a comprehensive evaluation of the USGS corrective action process in response to Recommendation 2 of the Fiscal Year 1997 Management Assessment was performed during the audit. A significant improvement in the effectiveness of corrective action process was observed with improvements needed only in the classification of conditions adverse to quality and in performance of root cause determinations. Overall, the audit determined that the corrective action process currently implemented by USGS is effective.

The audit team identified three conditions adverse to quality during the audit that resulted in the issuance of three Deficiency Reports (DR) detailed in Section 5.5.2. Two adverse conditions related to personnel qualification issues are detailed in Section 5.5.1, and were referred to a previously issued Corrective Action Request (CAR), USGS-98-C-004. Four conditions adverse to quality described in Section 5.5.4 were identified by the audit team and corrected prior to the post-audit meeting. Additionally, there were five recommendations, which are described in Section 6.0 of this report.

In performing this audit, consideration was given to previous Office of Quality Assurance (OQA) activities to support and evaluate USGS implementation of the QA Program. Specifically, prior to and subsequent to this audit, a task was ongoing by OQA to assist USGS in closing out a backlog of Nonconformance Reports (NCR) and statusing NCRs that cannot be readily resolved. This task has been effective in getting the backlog reduced and contributed to the ease in evaluation of this program element.

2.0 SCOPE

The audit was conducted to evaluate the adequacy of the compliance and the effectiveness of the OCRWM QA Program as described in the QARD and USGS implementing procedures.

The following QA Program elements/requirements were evaluated during the audit, in accordance with the approved audit plan:

QA PROGRAM ELEMENTS

1.0	Organization
2.0	Quality Assurance Program
4.0	Procurement Document Control
5.0	Implementing Documents
6.0	Document Control
7.0	Control of Purchased Items and Services
12.0	Control of Measuring and Test Equipment
15.0	Nonconformances
16.0	Corrective Action
17.0	Quality Assurance Records
Supplement I	Software
Supplement II	Sample Control
Supplement III	Scientific Investigation
Appendix C	Mined Geologic Disposal System

The following QA Program elements were not evaluated, since the USGS currently has no activities to which these elements apply:

3.0	Design Control
8.0	Identification and Control of Items
9.0	Control of Special Processes
10.0	Inspection
11.0	Test Control
13.0	Handling, Storage, and Shipping
14.0	Inspection, Test, and Operating Status
18.0	Audits
Supplement IV	Field Surveying
Supplement V	Control of the Electronic Management of Data
Appendix A	High-Level Waste Form Production
Appendix B	Storage and Transportation

3.0 AUDIT TEAM

The following is a list of audit team members and their assigned areas of responsibility:

<u>Name/Title/Organization</u>	<u>QA Program Element</u>
William J. Glasser, Audit Team Leader, OQA	1.0, 2.0, 5.0, 6.0
Kenneth O. Gilkerson, Auditor, OQA	2.0, 15.0, 17.0
Robert P. Hasson, Auditor, OQA	4.0, 7.0, 12.0, Appendix C
Charles C. Warren, Auditor, OQA	16.0
Lawrence W. McGrath, Auditor, OQA	Supplements I, II, and III

4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

Prior to initiation of the formal audit, on April 2, 1998, members of the audit team visited the Yucca Mountain Test Site to gather information concerning field implementation of selected quality program elements to be evaluated during the audit. The pre-audit meeting was held on April 6, 1998, at USGS offices in Denver, Colorado. Daily debriefing and coordination meetings were held with USGS management and staff, and daily audit team meetings were held to discuss audit status. The audit was concluded with a post-audit meeting on April 10, 1998, at USGS offices located in Denver, Colorado. Personnel contacted during the audit, including those who attended the pre-audit and post-audit meetings, are listed in Attachment I of this report.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that, overall, USGS implementation of the QA Program is adequate and is being satisfactorily implemented for the scope of the audit. The results for each program element evaluated are contained in Attachment 2, Summary Table of Audit Results for Procedural Compliance Evaluations.

In addition to the summary in Attachment 2, audit observations were noted and summarized as Recommendations in Section 6.0 below. Although the current USGS implementation of requirements is considered effective, the following QA Program Element areas have the potential to become ineffective and warrant management attention:

Document Control

Recommendation 3 addresses observations noted during the evaluation of Section 6 of the QARD, "Document Control." The details summarized in the recommendation are minor in themselves, however, continued inattention to these areas could result in loss of effective control over issued controlled documents.

Quality Assurance Records

Recommendation 4 addresses the timeliness of record submittal. During this audit, it was observed that submittal of records continues to be an issue. Several deficiency documents have been identified relative to timeliness of submitting records at USGS, one of which is still open (USGS-96-D-006).

Although implementation of QA Program Element 2.0 was determined to be acceptable overall, it should be noted that USGS Management is actively assessing deficient conditions associated with the qualifications of USGS and contractor personnel to formulate necessary corrective actions. This audit

confirmed additional examples of these problems which were previously identified in Corrective Action Request USGS-98-C-004. This is discussed in detail in Section 5.5.1.

5.2 Stop Work or Immediate Corrective Actions Taken

There were no Stop Work Orders, immediate corrective actions, or related additional items resulting from this audit.

5.3 QA Program Audit Activities

The Summary Table of Audit Results for Procedural Compliance Evaluations is provided in Attachment 2. The audit checklists contain the details of the audit evaluation and the identification of the objective evidence reviewed. The checklists are kept and maintained as QA Records.

5.4 Technical Audit Activities

There were no technical areas evaluated during this audit.

5.5 Summary of Deficiencies

The audit team identified deficiencies in four program areas which resulted in the issuance of three DRs and a referral to an existing USGS CAR. In addition, four deficiencies were identified by the audit team and corrected prior to the post-audit meeting.

Synopsis of deficiencies referred to an existing CAR, documented on new DRs, and those corrected during the audit are detailed below. The CAR and DRs have been transmitted under separate letters.

5.5.1 Corrective Action Requests

USGS-98-C-004

An evaluation of both USGS and contractor personnel qualification records disclosed additional examples of Position Descriptions which failed to clearly depict educational and experience requirements; e.g. position descriptions by Pacific Western Technologies for administrative personnel and USGS position descriptions for QA Implementation Specialists. Additionally an individual's qualification file included a "Letter of Attestation" that contained errors. These specifics, including personnel affected, were identified to the USGS Personnel Qualification/ Training Coordinator and are documented in the completed audit checklist. This deficiency was previously addressed in CAR USGS-98-C-004 (issued December 1997) to USGS regarding personnel qualifications relative to experience and education prerequisites. A

discussion was held with USGS management during this audit relative to the extent of condition and corrective action measures being considered for this CAR. It was emphasized that this response would need to address the additional examples identified during this audit.

5.5.2 Deficiency Reports

USGS-98-D-074

USGS Quality Management Procedure (QMP) 6.01, Revision 7, requires that controlled documents be available for use. Copies of controlled documents were in use in the calibration laboratory at the Nevada Test Site and at USGS without controlling as a sub-issue as allowed by the governing requirement. Further, it was observed that quality affecting work was not always performed to a “red stamped” controlled copy. In all cases, the revision levels of the documents were correct although not controlled.

USGS-98-D-075

USGS QMP 4.01, Revision 9-M1, governs the receipt and acceptance of items and services. Contrary to this procedure, one item had been received and accepted from a calibration supplier, Setra, without obtaining the procedure and revision level used for the calibration. Further, another receiving report was identified which omitted required information.

USGS-98-D-076

Contrary to the requirements of Administrative Procedure (AP)-16.1Q, “Performance/Deficiency Reporting,” two USGS PRs required further investigation to determine the impact/extent of the condition. These PRs should have been classified as deficiencies and documented on DRs so that all required types of corrective action (investigation of impact/extent of the deficiency) could have been performed and documented.

5.5.3 Performance Reports

None

5.5.4 Deficiencies Corrected During the Audit

Deficiencies that are considered isolated in nature and only requiring remedial action can be corrected during the audit. The following deficiencies were identified and corrected during the audit:

1. QMP 3.07, Revision 5-M2, YMP-USGS Review Procedure, requires that reviews be documented using the YMP-USGS Review/Comment Form. Contrary to this requirement, for reviews of QMP-2.08, Revision 3, and QMP-2.02, Revision 7, one individual used an incorrect electronic version of a document review form. With the exception of the correct governing procedure and type of review, the form contained all of the essential information required. Since no other examples were noted, either at USGS in process or in recent records submittals, USGS corrected the governing documents and noted the type of review conducted. Changes to both review records were reviewed by the auditor to verify that the changes were appropriate based on the nature of comments generated. This item was considered corrected during the audit.
2. QMP 6.01, Revision 7, requires that controlled copies of documents be issued to identified copy holders. During a recent relocation of the Associate Chief, ESIP, USGS, from one office complex to another, his copy of controlled documents were split between technical and quality procedures. Although the technical procedures were being maintained in a library for general use, this copy had been decontrolled and not assigned to an individual. As a result of this observation, the technical procedures were assigned to the document control clerk under her name to maintain these procedures. The auditor verified that the documents were under proper control prior to the completion of the audit. This item was considered corrected during the audit.
3. QMP 6.01, Revision 7, Document Control, requires that holders of controlled documents maintain controlled documents assigned to them. During review of one manual, it was noted that some copies of controlled "red stamped" copies were missing from the manual. During the course of the audit, no other examples were noted where properly controlled documents were missing. USGS provided properly controlled copies to complete the controlled set which was verified by the auditor prior to completion of the audit. This item was considered corrected during the audit.
4. During the audit, a review of several Scientific Notebooks (SN) was conducted. One, SN-0089A-C, had old page numbers lined out, new page numbers added or otherwise changed. No initial and date was indicated where changes were made. It was noted that this SN had not been submitted for final review and acceptance by USGS, and is considered open until this review occurs. USGS was proactive in that they corrected the S/N during the audit. This was determined to be an isolated incident.

5.5.5 Follow-up of Previously Identified CARs and DRs:

USGS-98-C-004

USGS is currently investigating and preparing a response to this CAR which documents issues related to personnel qualification. During the conduct of this audit, additional examples of the issues were identified and documented in Section 5.5.1 of this report.

USGS-98-C-007

USGS is currently investigating and preparing a response to this CAR which documents issues related to classification and evaluation of deficiencies. During the conduct of this audit, similar issues were identified where a deficiency was handled as a PR rather than as a DR. Although similar in nature, the specific issues identified on this audit are being handled on a separate DR as documented in Section 5.5.2 of this report.

USGS-96-D-006

The corrective actions for this deficiency, which addresses timely submittal of records, is currently in progress. During the conduct of this audit, it was observed that submittal of records continues to be an issue. This observation is summarized in Section 5.1 of this report.

6.0 Recommendations

1. It is recommended that the nine attachments to the training procedures QMP 2.07 be reevaluated and eliminated or consolidated into the Attachment being used. A review of training records to the procedure disclosed that the primary means of assigning and documenting training is on forms identified in Attachments 1 and 5, while other forms (Attachment 2) are never used. Other information depicted on attachments for training could be consolidated into one form or multi-use forms could be developed to more closely reflect how training actually occurs at USGS.
2. It was noted that an OQA Representative was approving “waivers of qualification” for outside personnel utilized by USGS. While a recent change to the USGS Organization procedures allows this, it is recommended that USGS re-evaluate procedures wherein the OQA Representatives assume all previous duties of the USGS QA Manager. In some cases, it is not appropriate for the OQA Representative to approve processes inherent to USGS internal operations.
3. Although not specifically noted as violations of requirements, several of the practices and attention to detail in management of document control is in need of attention as follows:

- During review of the distribution control system, it was noted that additional information regarding the date the document transmittal notice was sent, date returned, and date cancelled was maintained on the database. However, due to a recent “computer crash” the dates cannot be relied upon for valid information. This information should be maintained current to provide a useful management resource.
 - During review of the control system, it was noted that the computer system was relied upon to produce all of the data with regard to controlled copy holders. It is recommended that USGS maintain hard copies of the controlled copy holder distribution lists in a separate notebook.
 - During the audit, it was noted that controlled QMPs were kept in QMP identified binders, unmarked binders, and loose in a file. Some of the binders and files were not identified as to whom the controlled copies belonged. Since the individual copies of controlled copies are not uniquely identified to its holder (no. individual copy number) it is recommended that a consistent approach be applied to identify the “manual” which contains controlled documents. Further, consideration should be given to marking on each controlled document the holders identification number.
4. Several deficiency documents have been identified relative to the timeliness of submitting records at USGS, one of which is still open (i.e., USGS-96-D-006). It is recommended that USGS consider putting on formal training to USGS personnel who generate records (i.e., the Records Source) to ensure that all USGS personnel understand the submittal requirements that are identified in AP 17.1Q. It was noted during the evaluation of training in this audit that all training is currently by reading assignment and that no classroom training has been performed in recent years.
5. It is recommended that performance of root cause determinations by USGS give appropriate consideration to personnel errors and failure of management systems. Root causes identified as repetitive procedural problems or failure to apply QA Manual/procedures invariably stem from failure of personnel or management to function effectively. Appropriate corrective action to preclude recurrence cannot be identified without an accurate determination of root cause.

7.0 List of Attachments

Attachment 1: Personnel Contacted During the Audit

Attachment 2: Summary Table of Audit Results for Procedural Compliance Evaluations

ATTACHMENT 1

Personnel Contacted During the Audit **Las Vegas**

<u>Name</u>	<u>Organization/Title</u>	<u>Pre-Audit Meeting</u>	<u>Contacted During Audit</u>	<u>Post-Audit Meeting</u>
Anderson, A.	Secretary, EAG		X	
Brady, T.	ESIP Technical Publication		X	
Burnham, P.	Records Coordinator		X	
Chaney, T.	Chief, EA, USGS	X	X	X
Chornack, M.	Hydrologist, USGS		X	
Clayton, B.	Records Assistant		X	
Corbert, C.	Hydrologist Software, USGS			X
Craig, R.	Technical Project Officer, USGS		X	
Darnell, S.	QAIS/USGS	X	X	X
Golos, J.	Operations Specialist, USGS		X	X
Graves, R.	Hydrologist, USGS		X	
Guertal, W.	Hydrologist, USGS		X	
Habbe, R.	QA Engineering, OQA/QATSS		X	
Hersh, B.	EA Procurement USGS/PWT	X	X	X
Hommel, D.	Hydro/Cal Technician		X	
Horton, S.	OQA/QATSS		X	
Hudson, D.	Hydrologist		X	
Kwak, L.	Chemist, USGS		X	
Larsen, K.	Tech.Data Management .Specialist, USGS/PWT	X		
Lindberg, J.	QAISS, USGS/PWT	X		X
Lykins, A.	QA Specialist, USGS		X	
Marshall, B.	Hydrologist, USGS		X	
Maudlin, R.	QA Verification, OQA/QATSS		X	
Murry, M.	Administrative Assistant		X	
Mustard, M.	Hydrologist (EA) USGS	X	X	X
Neksibm N,	Training Coordinator, USGS		X	
Nelson, M.	Training Coordinator, USGS		X	X
O'Neill, M.	Administrative Assistant, USGS/TRW		X	
Paces, J.	Hydrologist, USGS		X	
Parks, B.	Associate Chief, ESIP, USGS		X	X
Rattray, G.	Hydrologist, USGS		X	
Romero, D.	Purchasing Agent, USGS		X	
Scofield, K.	Hydro Technician, USGS		X	
Sheaffer, P.	QA Implementation Specialist		X	
Simmons, K.	Geologist, USGS		X	
Sims, A.	Computer/Specialist./Hydro Technician, USGS		X	
Sinks, D.	Quality Assurance Specialist, OQA/QATSS – USGS	X	X	X
Soeder, D.	Field Operations Coordinator, USGS		X	
Striffler, P.	Hydrologist, USGS		X	
Wagner, L.	QA Verification, OQA/QATSS		X	
Whiteside, A.	Quality Assurance Specialist, OQA/QATSS – USGS	X	X	X
Yang, A.	Hydrologist, USGS		X	

ATTACHMENT 2
Summary Table of Audit Results
For Procedural Compliance Evaluations

ELEMENT	IMPLEMENTING DOCUMENTS	DETAILS (CHECKLIST)	DEFICIENCIES	RECOMMENDATIONS	PROGRAM ADEQUACY	PROCEDURE COMPLIANCE	OVERALL
1	DOE/RW-0333P, Rev. 7	Pgs. 1, 2	N	N	SAT	SAT	SAT
	YMP-USGS-QMP-1.01, Rev. 6	Pgs. 3-5	N	N	SAT	SAT	
2	YMP-USGS-QMP-3.07, Rev. 5, MOD 2	Pgs. 6-8 Pgs. 86-88	N	N	SAT	SAT	SAT
	QMP-2.02, Rev. 6, MOD 3	Pgs. 9-11	CAR USGS-98-C-004	N REC. #2	SAT	UNSAT	
	QMP-2.08, Rev. 2, MOD 3	Pgs. 12-14	CAR USGS-98-C-004	N	SAT	UNSAT	
	QMP-2.07, Rev. 3	Pgs. 15-20	N	REC. #1	SAT	SAT	
4	USGS-QMP-4.01, Rev. 9, MOD 1	Pgs. 21-23 Pg. 40	USGS-98-D-075	N	SAT	SAT	SAT
	USGS-QMP-4.02, Rev. 7	Pgs. 24-26	N	N	SAT	SAT	
5	YMP-USGS-QMP-5.01, Rev. 7	Pgs. 27-30	N	N	SAT	SAT	SAT
	YMP-USGS-QMP-5.03, Rev. 9	Pgs. 31-35	N	N	SAT	SAT	
6	YMP-USGS-QMP-6.01, Rev. 7	Pgs. 36-39	USGS-98-D-074	REC. #3	SAT	SAT	SAT
7	AP-7.4Q, Rev. 2	Pgs. 41, 42	N	N	SAT	SAT	SAT
12	USGS-QMP-12.01, Rev. 8	Pgs. 43-50	N	N	SAT	SAT	SAT
15	YAP-15.1Q, Rev. 3, ICN 1	Pgs. 51-53	N	N	SAT	SAT	SAT

ELEMENT	IMPLEMENTING DOCUMENTS	DETAILS (CHECKLIST)	DEFICIENCIES	RECOMMENDATIONS	PROGRAM ADEQUACY	PROCEDURE COMPLIANCE	OVERALL
16	AP-16.1Q, Rev. 2	Pgs. 54, 55	USGS-98-D-076	N	SAT	SAT	SAT
	AP-16.2Q, Rev. 2	Pgs. 56, 57	N	REC. #5	SAT	SAT	
	AP-16.4Q, Rev. 0	Pgs. 58-62	N	N	SAT	SAT	
17	DOE/RW033P QARD, Rev. 7	Pg. 63	N	N	SAT	SAT	SAT
	AP-17.1Q, Rev. 0	Pgs. 64-67	USGS-96-D-006	REC. #4	SAT	SAT	
SI	YMP-USGS QMP-3.03, Rev. 7	Pgs. 68-75	N	N	SAT	SAT	SAT
SII	YMP-USGS QMP-8.01, Rev. 4, MOD 1	Pgs. 76-80	N	N	SAT	SAT	SAT
	YAP-SII.4Q, Rev.1	Pgs. 81, 82	N	N	SAT	SAT	
SIII	USGS-QMP-5.05, Rev. 4	Pgs. 83-85	N	N	SAT	SAT	SAT
	USGS-QMP-3.04, Rev. 9	Pgs. 89-96	N	N	SAT	SAT	
SV		Pgs. 96a, b, c	N	N	N/A	N/A	N/A

LEGEND:

N..... None
N/A..... Not Applicable
SAT..... Satisfactory
UNSAT..... Unsatisfactory